



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 03 03797 002

Manufacturer:

**Hebei Topson
Medical Technology Co., Ltd.**

Room 003-204, Fangda science Park
No.266 Tianshan Street, New and high-tech District
050011 Shijiazhuang
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

Prolinx GmbH

Brehmstr. 56
40239 Duesseldorf
GERMANY

**Product
Category(ies):**

Positive Airway Pressure.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ1710901

Valid from:

2018-07-09

Valid until:

2023-07-08



Date, 2018-07-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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